

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

v.

LLOYD LANDSMAN,

Defendant.

17-cr-00653 (SIL)

SENTENCING MEMORANDUM OF DEFENDANT LLOYD LANDSMAN

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
EXHIBIT LIST	iii
PRELIMINARY STATEMENT	1
I. LLOYD LANDSMAN’S PERSONAL HISTORY AND CIRCUMSTANCES.....	3
A. Early Life and Family Background.....	3
B. Education and Medical Career.....	4
C. Personal Life	5
D. Mental Health and Financial Circumstances	7
II. PROBATION OFFICE’S PRESENTENCE INVESTIGATION AND REPORT.....	8
III. SECTION 3553(a) FACTORS STRONGLY FAVOR A SENTENCE OF RESTITUTION ONLY	9
A. Lloyd’s History and Circumstances.....	10
B. Nature and Circumstances of the Offense; Need for Sentence to Reflect the Seriousness of the Offense.....	10
C. Need for Sentence to Provide Specific Deterrence.....	22
D. Need for Sentence to Provide General Deterrence	24
E. Need to Avoid Unwarranted Sentence Disparities	24
CONCLUSION.....	27

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Gall v. United States</i> , 552 U.S. 38 (2007).....	9
<i>Kimbrough v. United States</i> , 552 U.S. 85 (2007).....	9
<i>United States v. Adelson</i> , 441 F.Supp.2d 506 (S.D.N.Y. 2006).....	10
<i>United States v. Monnier</i> , 718 F. Supp. 2d 1040 (D. Neb. 2010).....	9
<i>United States v. Park</i> , 758 F.3d 193 (2d Cir. 2014).....	9
<i>United States v. Scully</i> , 877 F.3d 464 (2d Cir. 2017).....	9
Statutes	
21 U.S.C. § 331.....	1
21 U.S.C. § 333.....	1
18 U.S.C. § 3553.....	<i>passim</i>
18 U.S.C. § 3582.....	9

EXHIBIT LIST

Exhibit

- A. Letter from Selma Landsman, dated August 24, 2018
- B. Letter from Brian Landsman, dated September 4, 2018
- C. Letter from Kathryn Landsman
- D. Letter from Bruce Kaplan, dated August 1, 2018
- E. Letter from Dawn Wagner, dated August 14, 2018
- F. Letter from Kelvin Blasse, dated August 13, 2018
- G. Letter from Amy Resnik, dated August 10, 2018
- H. Letter from Donna Landsman, dated August 11, 2018
- I. Letter from Albert Bacchi
- J. Letter from Daniel Dienst, dated August 1, 2018
- K. Letter from Frank Wetchler, dated July 30, 2018
- L. Letter from Brian Kerley, dated July 31, 2018
- M. Letter from David Matlin, dated August 3, 2018
- N. Sarah N. Lynch, *The “Botox Police:” FDA Criminal Office Draws Fire from Agents and Doctors over Drug Import Crackdown*, Reuters (Sept. 8, 2016)
- O. *President Of Pharmaceutical Companies Sentenced To 60 Months In Prison For Long-Running Scheme To Sell Misbranded And Unapproved Chemotherapy And Other Prescription Drugs*, U.S. DOJ (June 2, 2016)

Dr. Lloyd Landsman, by and through his undersigned counsel, respectfully submits this Sentencing Memorandum in support of his request to be sentenced to the \$250,000 forfeiture judgment set forth in his plea agreement (the “Forfeiture Order”) and a Special Assessment of \$25. For the reasons set forth below, neither a term of probation nor community service is necessary to achieve the objectives of sentencing.

PRELIMINARY STATEMENT

Lloyd Landsman is a dedicated plastic surgeon with a long history of providing excellent medical care to patients and emotional support to family, friends, patients, co-workers, and acquaintances. Dr. Landsman has run a successful medical practice for over twenty-five years and has not had a single encounter with law enforcement prior to this case.

On December 5, 2017, Dr. Landsman pleaded guilty to one misdemeanor count of receipt of misbranded drugs in interstate commerce and delivery thereof for pay, in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 331(c) and 333(a)(1), a strict liability offense for which no proof of intent is required. Dr. Landsman accepts full responsibility for the conduct underlying his guilty plea. Nonetheless, his actions must be placed in the proper context in order for the Court to determine a just sentence.

Botox is produced by Allergan, a large pharmaceutical company, at a facility located in Ireland. Allergan sells its products in bulk to various drug distributors and wholesalers, which then make smaller sales to medical facilities. Dr. Landsman violated the FDCA by ordering misbranded Botox from a Canadian drug wholesaler and thereafter administering the drug to patients. The Botox that Dr. Landsman purchased was not counterfeit or expired; it was genuine and Allergan-produced, and it was administered without incident. The Botox was only considered “misbranded” under the FDCA because its packaging lacked certain FDA-required warnings. The product itself was identical to properly-branded Botox, and not a single patient

was harmed by the Canadian-sourced Botox. Nor did Dr. Landsman's conduct have any effect on government-funded health programs or insurance companies, as his patients pay for Botox out-of-pocket. Moreover, Dr. Landsman was wholly unaware that he was committing a crime by ordering genuine Botox from a Canadian wholesaler. In light of these exact mitigating factors, the Department of Justice ("DOJ") declined to prosecute numerous other misbranded drug cases.

The Probation Office has recommended the following sentence for Lloyd: compliance with the Forfeiture Order, two years of probation, 200 hours of community service, a fine of \$5,000, and a Special Assessment of \$25. Probation Sentence Recommendation (June 29, 2018) ("PSR Rec."), at 1. The Probation Office also recommends a special condition that would prohibit Lloyd from opening any new financial accounts, whether for business or personal reasons, without first obtaining approval from the Probation Office. *Id.*

Any penalty beyond compliance with the Forfeiture Order and the Special Assessment is unnecessary in this case. Dr. Landsman is not wealthy and will be severely handicapped by a \$250,000 forfeiture payment, the humiliation of a federal criminal conviction on his record, and whatever further punitive measures the New York State Department of Health, Office of Professional Medical Conduct ("OPMC") deems appropriate, which are unknown at this point. Moreover, any further punishment beyond compliance with the Forfeiture Order and the Special Assessment will not serve as further deterrence either to Dr. Landsman, who wants nothing more than to put this case behind him, or to other physicians, who may find themselves in Dr. Landsman's shoes despite their best intentions, given that the crime does not require proof of *mens rea*.

I. LLOYD LANDSMAN'S PERSONAL HISTORY AND CIRCUMSTANCES

A. Early Life and Family Background

Lloyd Landsman was born on February 17, 1959, in New York, New York, to Stanley and Selma Landsman. Stanley was the owner of a clothing distribution center, and Selma earned her college degree after having children and worked several miscellaneous jobs throughout Lloyd's life. Stanley passed away in 2004 at age 74, and Selma currently resides in Boynton Beach, Florida. Lloyd also has two siblings – Ivy Landsman, age 61, and Marc Landsman, age 54. Ivy is a nurse and Marc works in real estate. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Letter from Selma Landsman, dated August 24, 2018, at 2 (Exhibit A).

Lloyd began dating his wife, Donna Landsman, in 1981, and they married on July 23, 1983. Donna is an attorney, and worked seventeen years as a Principal Court Attorney for a New York Supreme Court judge. Currently, Donna works for an insurance company as a claims manager. Lloyd and Donna have two adult children – Brian and Kathryn, both of whom graduated from the University of Pennsylvania. Brian is thirty-one and works for a software company. Kathryn is twenty-five and works for a surgical robotics company. Brian and Kathryn are Lloyd's pride and joy, and both have an immeasurable amount of love and respect for their father. See Letter from Brian Landsman, dated September 4, 2018 (Exhibit B); Letter from Kathryn Landsman (Exhibit C).

[REDACTED]

[REDACTED]

[REDACTED]

B. Education and Medical Career

Lloyd Landsman always wanted to be a doctor. *See* Letter from Selma Landsman, Ex. A, at 1. Lloyd attended college at the University of Michigan, during which he worked at a hospital in the neo-natal ICU feeding premature infants, conducted laboratory research on the causes of essential hypertension, and worked as a volunteer teacher in a pre-school. He majored in biology and graduated with honors in 1981 and then attended New York University School of Medicine. He received his Doctor of Medicine degree in 1985.

After medical school, Lloyd completed a six-year general surgery residency at Westchester Medical Center, which included a one-year fellowship in critical care. He then completed a three-year plastic surgery residency at the Mount Sinai School of Medicine in Manhattan. He achieved board certification in both General Surgery and Plastic Surgery. After he completed his training in 1994, Lloyd was recruited by the Chief of Surgery at the Good Samaritan Hospital in West Islip, Suffolk County, primarily to bring modern techniques in reconstructive breast surgery to a community with a high incidence of breast cancer. Lloyd served as the Chief of Plastic Surgery at Good Samaritan from 2004-2010.

In addition to his hospital work, Dr. Landsman has maintained a private practice since 1994 (first in West Islip, and currently in Smithtown, New York), where he performs surgery on both the face and body, as well as a number of non-surgical treatments, such as the administration of Botox and dermal fillers. He performs surgery out of an operating room located in his office, which is certified by the American Association for the Accreditation of Ambulatory Surgical Facilities. Dr. Landsman is also a member of the American Society for Aesthetic Plastic

Surgery, the American Society of Plastic Surgeons, and The New York State Society of Plastic Surgery.

In addition to cosmetic treatments, Dr. Landsman continues to perform reconstructive breast surgeries, and he does not charge breast cancer patients beyond what is covered by their insurance. Lloyd's number one priority is helping these patients regain their confidence after the physical and emotional trauma of breast cancer, and he often works in tandem with a tattoo artist to help patients cover up their surgical scars. *See* Letter from Bruce Kaplan, dated August 1, 2018 (Exhibit D). Dr. Landsman is beloved by his patients as a result of his high-quality care delivered with great compassion. *See* Letter from Dawn Wagner, dated August 14, 2018, at 2 (Exhibit E).

Dr. Landsman is also very close with the staff in his practice, and treats them with the same kindness and empathy with which he treats his family and friends. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See*

Letter from Kelvin Blasse, dated August 13, 2018 (Exhibit F).

C. Personal Life

Dr. Landsman's big heart and kind ways are not limited to the examination room. Among his family and friends, Lloyd is known as a kind, generous, and pure-hearted person to countless individuals. He is the godfather to six children from six different families, and he always bends over backwards to provide assistance to others. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Letter from Amy Resnik, dated August 10, 2018, at 3 (Exhibit G);
see also Letter from Donna Landsman, dated August 11, 2018, at 2 (Exhibit H) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Letter from Albert Bacchi (Exhibit I). That Lloyd would provide such a
level of support and devotion to someone whom he had just met is truly a reflection of the type
of person and doctor that he is. See also Letter from Daniel Dienst (Exhibit J) [REDACTED]

[REDACTED]

[REDACTED] Letter from Frank Wetchler, dated July 30,
2018 (Exhibit K) [REDACTED]

[REDACTED]

[REDACTED]

Medicine is more than just an occupation and source of income for Lloyd; it provides him
with an incredible platform through which he can lift others up in times of need. However,
Lloyd's kindness and generosity is not limited to the skills he learned in medical school. When
Brian and Kathryn were in grade school, Lloyd created a program in their school district that
provided tutoring to students who could not afford private tutors. Lloyd still participates in this
program today, tutoring students in both biology and history. Put simply, Lloyd has a passion for
improving the lives of others in any way that he can.

D. Mental Health and Financial Circumstances

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Combine that with the loss of 60% of his revenue during the recession, and the result is that Lloyd does not live the comfortable life that many surgeons do. He has struggled financially throughout the years. Lloyd has borrowed money from his mother, a close friend, and his sister-in-law to help him when his business was not doing well, and from his son to pay his legal bills. Some of these loans are still outstanding. But even when money was especially tight, Lloyd never lowered his employees' salaries. He also liberally provides complimentary treatments to friends, family members, and staff. While performing procedures free of cost may not be the most business-savvy course of action, it is compensation enough for Lloyd when he sees the self-esteem of his loved ones increase as the result of his hard work.

[REDACTED]

II. PROBATION OFFICE'S PRESENTENCE INVESTIGATION AND REPORT

In computing the recommended sentence, the Probation Office first applied a base offense level of six. Presentence Investigation Report ("PSR") at 6 (citing USSG § 2N2.1). It then applied a two-level decrease due to Lloyd's acceptance of responsibility. *Id.* (citing USSG § 3E1.1(a)). The Probation Office also computed a Criminal History Score of zero, which places Lloyd in Criminal History Category I. *Id.* (citing USSG Ch. 5, Pt. A (sentencing table)). Based on a Total Offense Level of four and a Criminal History Category of I, the Guidelines provide the following ranges:

Custody range: zero to six months (citing USSG § 5C1.1(b));

Supervised release range: one year (citing USSG § 5D1.2(a)(3));

Probation range: no more than three years (citing USSG § 5B1.2(a)(2));

Forfeiture: as provided by statute (citing USSG § 5E1.4);

Fine range: \$500-\$9,500 (citing USSG §§ 5E1.2(c)(3)).

Id. at 15.

The Probation Office has recommended a sentence of two years' probation, a \$5,000 fine, and the following special conditions:

- the defendant shall comply with the Forfeiture Order;
- the defendant shall complete 200 hours of Community Service at a location approved by the U.S. Probation Department;
- upon request, the defendant shall provide the U.S. Probation Department with full disclosure of his financial records, including co-mingled income, expenses, assets and liabilities, to include yearly income tax returns. With the exception of the financial accounts reported and noted within the presentence report, the defendant is prohibited from maintaining and/or opening any additional individual and/or joint checking, savings, or other financial accounts, for either personal or business purposes, without the knowledge and approval of the U.S. Probation Department. The defendant shall cooperate with the Probation Officer in the investigation of his financial dealings and shall provide truthful monthly statements of your income and expenses. The defendant shall cooperate in the signing of any necessary

authorization to release information forms permitting the U.S. Probation Department access to your financial information and records;

- The defendant shall notify the New York State Department of Health, Office of Professional Medical Conduct of his conviction, and provide proof that notification was made to the U.S. Probation Department.

PSR Rec. at 1. Lloyd's plea also carries a mandatory \$25 Special Assessment. *See* 18 U.S.C. § 3013(a)(1)(A)(iii).

III. SECTION 3553(a) FACTORS STRONGLY FAVOR A SENTENCE OF RESTITUTION ONLY

While the Guidelines range is the “starting point and the initial benchmark” in calculating a sentence, *Kimbrough v. United States*, 552 U.S. 85, 108 (2007) (quoting *Gall v. United States*, 552 U.S. 38, 49 (2007)), the Court must also consider the factors enumerated in 18 U.S.C. § 3553(a) before imposing a sentence. *See, e.g., United States v. Park*, 758 F.3d 193, 197 (2d Cir. 2014) (citing 18 U.S.C. § 3582(a)).

Section 3553(a) states that “[t]he court, in determining the particular sentence to be imposed, shall consider, (1) the nature and circumstances of the offense and the history and characteristics of the defendant; (2) the need for the sentence imposed . . . ; (3) the kinds of sentences available; (4) [the Guidelines range]; (5) any pertinent policy statement . . . ; (6) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and (7) the need to provide restitution to any victims of the offense.” Federal law is clear that a court should impose a sentence “sufficient, but not greater than necessary”:

- (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
- (B) to afford adequate deterrence to criminal conduct;
- (C) to protect the public from further crimes of the defendant; and

(D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C. § 3553(a) & (2).

Under the dictates of § 3553(a), “‘necessary’ is the ‘operative’ word, for section 3553(a) expressly dictates that ‘[t]he court shall impose a sentence sufficient, *but not greater than necessary*,’ to comply with the purposes set forth in paragraph (2) of this subsection.” *United States v. Adelson*, 441 F.Supp.2d 506, 515 (S.D.N.Y. 2006).

In this case, the § 3553 factors strongly support a sentence limited only to compliance with the Forfeiture Order and the Special Assessment. A term of probation and community service would be draconian.

A. Lloyd’s History and Circumstances

The conduct underlying Lloyd’s plea agreement is an unfortunate blemish on an otherwise noble life and career. Lloyd has always gone above and beyond for his patients and used his medical skills generously, even when there was no profit or professional gain for him. Lloyd has an immense passion for medicine and for helping others, and he is beloved by his family, friends, and patients. Lloyd’s misdemeanor plea is a stark outlier to the rest of his personal and professional life.

B. Nature and Circumstances of the Offense; Need for Sentence to Reflect the Seriousness of the Offense

Section 3553(a)(1) requires the Court to consider “the nature and circumstances of the offense,” while Section 3553(a)(2)(A) requires the Court to impose a sentence “sufficient, but not greater than necessary . . . to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense.” Consideration of these factors warrants leniency.

As discussed further below, the prosecution of misbranded drug cases has been looked at with skepticism by both the Food and Drug Administration (“FDA”) and the DOJ, as the majority of cases involve no harm to patients or the public and are completely void of criminal intent. Indeed, in this case, there is no dispute that Lloyd purchased genuine Botox that only differed from properly branded Botox by way of its labeling. Moreover, Lloyd did not submit any claims for the administration of Botox to health care programs or insurance companies, and thus no insurance or health care fraud is at issue in this case. Finally, there is no indication that Lloyd acted with criminal intent.

i. Background On Misbranded Drug Prosecutions

Lloyd accepts full responsibility for the actions that led to his guilty plea. Nonetheless, it is necessary to put the prosecution of misbranded Botox into the proper context to address the severity level of the crime as required by § 3553(a). In particular, both the DOJ and the FDA’s own agents have viewed such prosecutions with skepticism, particularly where, as here, criminal intent is lacking.

a. Reuters Investigation

In September 2016, Reuters published an article detailing findings from an investigation it conducted into criminal referrals by the FDA to the DOJ concerning misbranded drugs, and in particular, misbranded Botox. *See* Sarah N. Lynch, *The “Botox Police:” FDA Criminal Office Draws Fire from Agents and Doctors over Drug Import Crackdown*, Reuters (Sept. 8, 2016) (hereinafter the “Reuters Article”) (Exhibit N). Pursuant to a Freedom of Information Act request, Reuters reviewed more than 170 letters from the Department of Justice regarding such referrals, and concluded that “[p]rosecutors are declining to pursue many FDA cases, citing a lack of prosecutorial merit, criminal intent or strong evidence.” *Id.* at 3.

Reuters also spoke to a number of FDA agents about misbranded drug referrals, who were especially critical of the agency's handling of misbranded Botox cases:

Some FDA agents complain they have turned into the “Botox Police” – chasing down every doctor who purchased authentic versions of the popular anti-wrinkle drug that were labeled for use in other countries, an exercise producing few prosecutions. . . .

Concerns about the agency's handling of Botox cases emerged as early as 2013. In one field office, a psychologist sent to defuse internal tensions heard complaints of “micromanagement” of cases and of Botox inquiries wasting “valuable agent time” and antagonizing relations with U.S. attorneys, documents show. . . . Some complain the crackdown protects pharmaceutical companies' drug prices more than consumers.

Id. at 3, 5. Moreover, “[c]urrent and former FDA agents say managers push cases that lack legal merit at the expense of others with more potential that were not pursued, including probes involving steroids, the street-level sale of counterfeit painkillers and the importation of drugs like Kratom, a plant used as an alternative to opioids.” *Id.* at 4.

Further, in contrast to cases that present the potential for insurance or health care fraud, Reuters concluded that:

Investigations into doctors who purchase foreign unapproved cosmetic products are unlikely to prompt prosecutors to press charges, records and interviews show. There is little demonstrable harm to public health or the national purse since taxpayer-funded insurance programs do not accept claims for Botox unless it has been prescribed for an approved medical purpose.

Id. at 6.

Essentially, there is understandable concern surrounding the criminal prosecution of doctors who purchase genuine Botox that is simply mislabeled. Indeed, a review of the letters that Reuters obtained from the DOJ revealed that prosecutors have declined cases when “the Botox was authentic, small amounts were purchased, and no insurance claims were submitted.” *Id.* Additionally, prosecutors often “cited a lack of criminal intent in turning down FDA cases.”

Id. at 8. As the U.S. Attorney for the Eastern District of Missouri stated to Reuters, “[y]ou don’t have to be a philosopher king to understand there is an elemental unfairness in holding someone criminally liable for conduct of which they had no knowledge or intent.” *Id.* at 9.

b. The Prosecution of Dr. Anindya Sen and Patricia Posey Sen

One case is particularly illustrative of how misbranded drug cases are viewed by the DOJ when criminal intent is lacking. In June 2013, Dr. Anindya Sen, an oncologist, and his wife, Patricia Posey Sen (‘Posey’), were indicted in the Eastern District of Tennessee for their alleged role in a misbranded drug scheme. *See United States v. Sen, et al.*, No. 2:13-cr-00056 (E.D. Tenn.) (‘Sen Docket’). Posey was the manager of Dr. Sen’s medical practice and was accused of ordering a number of misbranded chemotherapy drugs, which were then administered to patients at the clinic. *See Sen Docket*, ECF No. 1, at 1, 7. The Sens were also accused of submitting fraudulent reimbursement claims to Medicare and other health benefits programs. *See id.* at 7.

After several superseding indictments were returned, Dr. Sen was tried on twenty-nine misdemeanor counts of causing the introduction into interstate commerce of misbranded drugs in violation of 21 U.S.C. § 331(a). *Sen Docket*, ECF No. 94. Posey was tried on the same twenty-nine misdemeanor counts, as well as seven felony counts of receiving misbranded drugs, forty-five counts of health care fraud, and two counts of making false statements to FDA agents. *Id.* Critically, unlike misdemeanor charges under the FDCA, felony charges require the government to prove that a defendant acted with the intent to defraud or mislead. *See* 21 U.S.C. § 333(a)(2).

In December 2013, the Sens were convicted of the twenty-nine misdemeanor misbranding counts, but Posey was acquitted of all of the remaining charges, *i.e.*, all of the charges requiring proof of knowledge or intent. *See Sen Docket*, ECF No. 134. The Sens appealed their convictions to the Sixth Circuit, and the National Association of Criminal Defense

Lawyers (“NACDL”) filed an *amicus curiae* brief, arguing that strict liability offenses should be reserved for very rare circumstances and that the Sens’ case was ill-fitted for strict liability charges. *See United States v. Sen*, No. 14-5772 (6th Cir.), ECF No. 19 (“NACDL Brief”). The NACDL argued that the Sens’ case was “the definition of prosecutorial overreach” because, among other things, “there is no dispute that Dr. Sen and his wife provided exceptional care,” there was no claim “that the mislabeled drugs they received were dangerous because of that mislabeling or materially different from the equivalent brand name drugs,” and the Sens were unaware that the mail-order pharmacy from which they purchased the misbranded drugs was under criminal investigation. NACDL Brief at 13. The NACDL also argued that strict liability crimes distort the plea bargaining process, particularly when a parallel felony charge is available:

If the government must not prove intent, it is given a huge cudgel with which to beat a defendant into submission: take this plea because we do not need to prove much at trial. This gives the government, which already has a significant advantage, *all* the cards in plea negotiations. Furthermore, where the government has a strict liability felony with which it can plausibly charge a defendant in addition to misdemeanor charges – as it did here – that advantage is further enhanced.

Again, the FDCA provides the emblematic example. The government can threaten someone who has merely received mislabeled drugs or adulterated food with a felony charge effectively to force her to accept a misdemeanor charge even though the person had no criminal intent. The threat of a felony charge is a massive hammer that assuredly distorts the plea bargaining process in the context of strict liability crimes.

NACDL Brief at 15. Indeed, as referenced in the NACDL Brief, the district judge who presided over the Sens’ case questioned at sentencing why the Sens bothered to go through with a trial on charges that did not require proof of criminal intent. *Id.* at 16.

The government did not file an opposition to the Sens’ or the NACDL’s appellate briefs. To the contrary, on December 15, 2014, the government filed a motion asking the Sixth Circuit to vacate the Sens’ judgments of conviction and remand to the district court for dismissal of the

indictment with prejudice. *See* No. 14-5772 (6th Cir.), ECF No. 27. The Sixth Circuit granted the government's motion on January 16, 2015, and several weeks later the government filed a motion to dismiss in the district court, stating the following:

Following the entry of judgment in this case, and while the defendants' appeals were pending, the Department of Justice reviewed its charging practices under 21 U.S.C. § 331 in cases involving the interstate distribution of misbranded or adulterated articles. The Department focused on, *inter alia*, the appropriate legal provisions for charging persons who order or purchase such articles for delivery to themselves from a distributor in another state or another country. Although consideration of those issues is still ongoing, the Department ultimately decided not to pursue charges under 21 U.S.C. 331(a) on the facts presented in this particular case.

Sen Docket, ECF No. 196. The district court granted the government's motion, fully exonerating the Sens. *See id.* at 197.

ii. Lloyd's Conduct

Dr. Landsman's case reflects precisely the concerns raised in the Reuters Article as well as the DOJ's dismissal of the charges against the Sens, as he did not harbor any criminal intent and his actions posed no risk of harm to his patients or the public.

a. No Criminal Intent

In or around 2013, Dr. Landsman was referred by several colleagues to the website of a company called "Medica Depot," which was based in Ontario and sold Canadian-sourced medical products. Lloyd began to purchase Botox from Medica Depot because it was less expensive than the Botox being offered by U.S.-based drug wholesalers, and the lower price enabled him to lower his prices to patients. He was unaware that it was illegal. The Botox that Lloyd purchased from Medica Depot was *identical* to U.S.-sourced Botox, as both were produced in Allergan's facility in Ireland and subsequently shipped on dry ice in Styrofoam containers. The products differed only in the sense that the packaging of the Botox from Medica

Depot lacked certain warnings required by the FDA. Specifically, the packages did not contain black box warning inserts, nor did the labels on the vials include the phrase “Rx only.” Thus, unbeknownst to Dr. Landsman, the Botox was technically “misbranded.”

In the summer of 2013, FDA agent Thomas Naksiata visited Dr. Landsman’s office and spoke with Karen Salant, Dr. Landsman’s office manager at the time. Agent Naksiata did not have a warrant, nor did he display a badge or any other feature that identified him as a law enforcement official. At Agent Naksiata’s request, Karen showed him a bottle of Botox. Agent Naksiata informed Karen that the bottle was technically “misbranded” due to its labeling and left her a business card, but no further information. Upon learning of Agent Naksiata’s visit, Dr. Landsman researched the validity of Canadian-sourced Botox, but did not come across anything that led him to believe that such products were improper to use or in any way different from the Botox available for purchase in the U.S.

Lloyd continued to use Canadian-sourced Botox without incident until February 2016, when he received a letter from U.S. Customs informing him that a shipment he ordered was being held for inspection at John F. Kennedy Airport. At that point, Lloyd ceased ordering Botox from Medica Depot. In or around February or March 2016, Agent Naksiata returned to Dr. Landsman’s office and spoke with then-patient coordinator Dawn Wagner, and instructed her that misbranded Botox should no longer be used. As detailed in Dawn’s letter, Agent Naksiata “appeared unofficial in his attire and did not show any official identification or badge” and “did not seem to [Dawn] to be a law enforcement official.” Letter from Dawn Wagner, Ex. E, at 2. Although Agent Naksiata left Dawn his card to pass on to Lloyd, he left “no other official paperwork or instructions.” *Id.*

Dr. Landsman deeply regrets not promptly contacting Agent Naksiata, and if he had any idea that he was under criminal investigation at the time he would have addressed the situation immediately. However, because he promptly stopped ordering Botox from Medica Depot upon receiving the letter from U.S. Customs, and because Agent Naksiata's visit was not described to him in a way that suggested urgency, he regrettably procrastinated making contact.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] While Lloyd does not contend that these personal circumstances excuse his failure to contact Agent Naksiata, they are illuminative of his state of mind at the time.

Lloyd took several weeks off from work following his mother-in-law's death, and to his shock, he returned to the office in June 2016 to find a grand jury subpoena waiting for him. Upon finally realizing the gravity of the situation, Lloyd immediately contacted an attorney, Eliot Bloom, who helped him produce documents in response to the subpoena. Unfortunately, Mr. Bloom was temporarily suspended from practice in October 2016, which Lloyd relayed to Agent Naksiata.

In November 2016, Agent Naksiata returned to Dr. Landsman's office to discuss his compliance with the subpoena. Lloyd met with Agent Naksiata *without an attorney*, and was under the impression that he was coming close to a resolution of the matter. At one point during the meeting, Lloyd asked if there was anything he could sign to acknowledge that he had done something wrong and to commit that he would not order misbranded Botox again. Agent Naksiata pulled out an Acknowledgement form that was pre-typed on FDA letterhead, which Lloyd then signed. Although the form states that Lloyd understood that his actions amounted to a

crime, he believed that signing the form would result in a non-criminal resolution. In hindsight, Lloyd deeply regrets not having an attorney present at this meeting.

In August 2017, nine months after the meeting in Lloyd's office, Agent Naksiata informed Mr. Bloom that Lloyd should retain new counsel because the case needed to move forward regardless of whether Mr. Bloom was still on suspension. Lloyd then hired new counsel and awaited a resolution of the case, believing that the matter was administrative or regulatory rather than criminal and that he would be subject to a fine, at most. Lloyd was unfortunately incorrect, and in November 2017, with the government using the "huge cudgel [of a felony charge]" with which to beat a defendant into submission (*see* NACDL Brief at 15), criminal plea negotiations began. Ultimately, a plea agreement was offered to Lloyd on the Tuesday before Thanksgiving, and he was informed that if he did not accept the deal by the following Monday, the government intended to move forward with a grand jury investigation on a felony charge. Understanding that he was guilty of a misdemeanor due to the sole fact that he had in fact purchased misbranded Botox, Lloyd accepted the plea offer.

In sum, while Lloyd understands that his state of mind is irrelevant to a strict liability charge, it is nonetheless appropriate for the Court to grant him leniency at sentencing in light of his genuine ignorance to the fact that he was breaking the law by purchasing Botox from Medica Depot. As discussed above, one U.S. Attorney's Office even took the extreme measure of dropping charges following a guilty verdict after the structure of the verdict made clear that the jurors did not think that the defendants acted with criminal intent.

b. No Physical Harm to Lloyd's Patients

As explained above, the only difference between the Botox that Lloyd purchased from Medica Depot and properly branded Botox is in the packaging of the products. Thus, the

physical effects that Lloyd's patients achieved from Canadian-sourced Botox, which he always administered in a manner consistent with his years of experience and professional credentials, were identical to those that they would have achieved had he used U.S.-sourced Botox. Indeed, Lloyd has received zero patient complaints concerning adverse effects from the Botox he purchased from Medica Depot. In fact, Lloyd used the Canadian-sourced Botox on his own wife, mother, son, sister, and office staff, and would have never used the product if he had even the slightest doubt as to its safety.

Moreover, the risks associated with Botox that necessitate its black box warning are largely irrelevant to Lloyd's practice. Although Botox injections can present dangers if the drug spreads from the injection site to unintended parts of the body, such problems have occurred "mainly in patients who received overdoses of the drug for unapproved treatments, like limb spasticity in children with cerebral palsy." Natasha Singer, *F.D.A Orders Warning Label for Botox*, N.Y. Times (Apr. 30, 2009). In contrast, according to the FDA, "Botulinum toxins are safe when administered for approved uses at approved doses." *Id.*; see also Salynn Boyles, *Black Box Warning for Botox*, WebMD (Apr. 30, 2009) ("'If the drug is given the way it is intended, as described on the label, the risk of distant spread may well be zero,' said Ellis F. Unger, MD, of the FDA's Center for Drug Evaluation and Research.").²

Thus, because the Botox used by Lloyd was genuine and the treatments were always performed correctly, no patient was ever physically harmed from receiving misbranded Botox injections from Lloyd.

² Further, even if the black box warning were relevant to Lloyd's practice, it is hard to imagine how the failure of the warning's inclusion in each individual package of Botox would present harm to his patients. As a reputable physician, Lloyd is fully versed in any risks associated with the drugs that he administers to patients, and he provides all appropriate disclaimers to his patients during their consultations. In other words, there would be no difference in the quality of his treatment had the Botox from Medica Depot contained black box warning inserts, as Lloyd has no need to review the same warning each and every time he opens a new bottle of Botox.

c. No Financial Harm to Patients or Health Care Programs

In addition to causing no physical harm, Lloyd's use of "misbranded" Botox did not financially harm his patients, as Lloyd passed onto his patients the savings he obtained from purchasing Canadian-sourced Botox. At the time Lloyd began purchasing Botox from Medica Depot, domestically sourced Botox sold for around \$500 for 100 units. When Lloyd purchased Botox from U.S.-based distributors, he charged \$600 for a three-area Botox treatment. He also included a complimentary touch-up to improve patient satisfaction. However, Lloyd eventually learned that he could purchase the same product from Medica Depot for \$359 for 100 units. Thus, after he began purchasing Canadian-sourced Botox, Lloyd lowered his price to patients to \$500 for a three-area treatment, with the same complimentary touch-up included. He also frequently offered a 20% discount that enabled patients to purchase the same treatment at \$400, and sometimes even discounted his prices to \$300 for a three-area treatment and \$150 for a two-area treatment, again including the complementary touch-up. In contrast, a three-area Botox treatment by similarly credentialed physicians can run as high as \$1000.

Further, no health care programs or insurance companies were financially harmed by Lloyd's use of misbranded Botox, as he did not submit to them any claims for the administration of misbranded Botox. This alone makes Lloyd's case different than the majority of cases that have been prosecuted under the FDCA's misbranding statute. *See* Reuters Article at 6 (stating the prosecutors are unlikely to charge doctors who purchase misbranded cosmetic products because "[t]here is little demonstrable harm to public health or the national purse since taxpayer-funded insurance programs do not accept claims for Botox unless it has been prescribed for an approved medical purpose"). Moreover, even the case against the Sens, which involved the

submission of Medicaid claims for misbranded chemotherapy drugs, was ultimately dropped by the DOJ after it became clear that the Sens did not act with criminal intent.

d. The Court Should Disregard Any References in the Presentence Investigation Report to Dermal Fillers or Purchases from Pharmalogical Inc.

The PSR contains numerous references to Dr. Landsman's purchase of dermal fillers that are factually erroneous and/or irrelevant to the conduct underlying the guilty plea. First, the PSR repeatedly insinuates that Botox and dermal fillers are in the same class of products. This is incorrect. Botox is a neurotoxin that causes temporary paralysis of skeletal muscles, and is classified by the FDA as a "drug."³ On the other hand, dermal fillers are mainly used to provide volume and contour improvements in the face, and are classified by the FDA as "medical devices."⁴ Accordingly, certain phrases in the PSR, such as "[d]ermal fillers, including Botox" (*see* PSR ¶ 4), are plainly inaccurate. Further, while the FDA necessitates a black box warning for Botox, no such warning is required for dermal fillers. Thus, unlike the "misbranded" Botox which Dr. Landsman purchased and for which he has accepted responsibility, the dermal fillers referenced in the PSR were not missing black box warnings and were not contraband.

Moreover, the PSR attempts to implicate Dr. Landsman for a number of Botox and dermal filler purchases that he made from Pharmalogical Inc. ("Pharmalogical") from 2010 to 2013, none of which were part of his plea allocution. While Lloyd understands that the Court is entitled to consider uncharged conduct in imposing a sentence, the context in which he purchased products from Pharmalogical is critical.

³ *See* <https://www.fda.gov/Drugs/DrugSafety/ucm175011.htm> ("Drug Safety and Availability"); https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5232lbl.pdf (Botox Label).

⁴ *See* <https://www.fda.gov/MedicalDevices/ucm2007470.htm> ("Dermal Fillers").

Pharmalogical (also known as “Medical Device King”) was a New York-based drug wholesaler that, unbeknownst to Lloyd and many other physicians, was under investigation for selling misbranded, foreign-sourced drugs and medical devices at the time that Lloyd made the purchases referenced in the PSR. *See United States v. Scully*, 877 F.3d 464, 470 (2d Cir. 2017) (explaining that Pharmalogical would purchase misbranded drugs from foreign countries and then “misrepresent[] those products to medical professionals as FDA-approved”); *see also* DOJ Press Release, dated June 2, 2016 (attached as Exhibit O) (“Evidence elicited at trial from 40 witnesses established that [the president of Pharmalogical] deceived a wide array of doctors and cancer clinics into believing that he was selling legitimate FDA-approved products when, in reality, he was selling unapproved products imported through a series of unidentified middlemen in Turkey and elsewhere overseas.”). In fact, in June 2013, Lloyd received a letter from the FDA informing him of Pharmalogical’s misconduct. Thus, while the government has acknowledged that Dr. Landsman and other physicians were victims of Pharmalogical, the Probation Office is attempting to use the very same set of facts to besmirch Lloyd in his own case. Moreover, even though Lloyd has pleaded guilty to a strict liability crime, it would be unnecessarily punitive to hold him further accountable for making what he believed were innocuous purchases from a drug wholesaler that was located in New York.

Accordingly, the Court should decline to consider Lloyd’s purchase of dermal fillers or any of his purchases from Pharmalogical in assessing a proper sentence.

C. Need for Sentence to Provide Specific Deterrence

Section 3553(a)(2)(C) requires the Court to take into consideration the need “to protect the public from further crimes of the defendant.” This factor should not concern the Court, as Dr. Landsman poses no threat of recidivism.

Dr. Landsman ceased ordering Canadian-sourced Botox in February 2016 after he received the letter from U.S. Customs informing him that his shipment was being held at John F. Kennedy Airport.⁵ He is humbled and humiliated by this experience and will face a great financial strain as a result of the Forfeiture Order. Moreover, any punishment imposed by this Court is only the beginning for Lloyd, who still must face OPMC and the numerous penalties it has available at its disposal, which include community service, censure and reprimand, and license suspension.⁶ Any additional punishment beyond the Forfeiture Order and the Special Assessment will reverberate and impact OPMC and thereby place Lloyd at great risk for a harsh penalty from them. Unfortunately, even then Lloyd's battle is not over. Once OPMC renders a decision, hospitals may decide to revoke his privileges, and insurance carriers, on which Lloyd relies in order to perform reconstructive surgeries, may cut ties with him. Thus, the punishment imposed by this Court may have career-killing consequences, and Lloyd faces severe penalties irrespective of any leniency provided by the Court.

In short, Lloyd wants nothing more than to put this incident behind him. His number one priority is keeping his medical license intact so he can continue doing what he loves, and he has zero incentive to do anything to further jeopardize the career that he has spent a lifetime building. Accordingly, a sentence that is limited to compliance with the Forfeiture Order is more than a sufficient deterrent for Lloyd.

⁵ The PSR states that "between March 10, 2016, and July 8, 2016 (which includes a time period after being notified of the seized parcel), the defendant ordered \$13,485 worth of Botox, Juvederm Ultra 4, Juvederm Voluma with Lidocaine, and Dysport." PSR ¶ 9. This is false. As discussed above, the PSR erroneously conflates Lloyd's purchases of Botox, a drug for which the FDA requires a black box warning, with dermal fillers, which are medical devices that require no such warning.

⁶ See Understanding New York's Medical Conduct Program - Physician Discipline, N.Y. State Department of Health, *available at* <https://www.health.ny.gov/publications/1445/>.

D. Need for Sentence to Provide General Deterrence

Section 3553(a)(2)(B) requires the Court to take into consideration the need to “afford adequate deterrence to criminal conduct,” often viewed as the need to provide general deterrence. This factor does not require a sentence beyond the Forfeiture Order and the Special Assessment for Lloyd.

First, given that Lloyd has pleaded guilty to a strict liability crime that requires no proof of intent, the correlation between the severity of his sentence and deterrence to other physicians, who may end up unknowingly committing the crime regardless, is questionable. *See, e.g., United States v. Monnier*, 718 F. Supp. 2d 1040, 1057 (D. Neb. 2010) (“The deterrent value of a longer sentence is marginal in the context of a strict liability scheme.”). Moreover, it is hard to imagine that other physicians would learn of Lloyd’s federal misdemeanor conviction and the significant restitution that he is now required to make, yet still purchase misbranded Botox because no other additional penalties were imposed by the Court. Such cost-benefit analysis would defy logic, as any monetary savings would be insignificant as compared to the risk of a criminal conviction, significant restitution, and potentially irreparable career damage.

Accordingly, a sentence that is limited to the Forfeiture Order and the Special Assessment is adequate to provide general deterrence.

E. Need to Avoid Unwarranted Sentence Disparities

Lloyd is somewhat limited in analyzing sentences of similarly situated defendants, as prosecutors routinely decline to bring criminal charges when a doctor is discovered to have purchased genuine products that were simply mislabeled, particularly when no alleged insurance fraud is at issue. *See Reuters Article at 3, 6* (“Prosecutors are declining to pursue many FDA cases, citing a lack of prosecutorial merit, criminal intent or strong evidence, Reuters found in a review of more than 170 letters detailing why the Department of Justice declined cases. . . .

[P]rosecutors declined cases because the Botox was authentic, small amounts were purchased, and no insurance claims were submitted.”).

However, one case in particular does provide a helpful comparison for the Court. In 2009, seven individuals (five doctors and two staff members) who worked at the Plastic Surgery Group, LLP in Albany each pleaded guilty in the Northern District of New York to one misdemeanor count of misbranding in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(1) as a result of the group’s purchase and use of a non-FDA approved Botulinum Toxin Type A drug produced by Toxin Research International, Inc. (“TRI-toxin”) in lieu of FDA-approved, Allergan-produced Botox. *See United States v. De Luca*, No. 1:09-cr-00425 (N.D.N.Y.); *United States v. Hargrave*, No. 1:09-cr-00426 (N.D.N.Y.); *United States v. Rockmore*, No. 1:09-cr-00427 (N.D.N.Y.); *United States v. Lynch*, No. 1:09-cr-00428 (N.D.N.Y.); *United States v. Noonan*, No. 1:09-cr-00429 (N.D.N.Y.); *United States v. Slattery*, No. 1:09-cr-00430 (N.D.N.Y.); *United States v. Knott*, No. 1:09-cr-00431 (N.D.N.Y.) (collectively the “PSG Defendants”). A critical difference between these cases and Lloyd’s case is that the patients treated by the PSG Defendants were not only injected with a drug that was different than Allergan-produced Botox, but they believed that they were in fact being treated with genuine Botox. *See, e.g., DeLuca Plea Agreement*, No. 1:09-cr-00425, ECF No. 3, at 5. Further, the PSG Defendants failed to notify affected patients that they had been injected with the wrong product, which the court found to be an aggravating factor at sentencing:

I understand from what everybody said today and I accept as true that at some point in late 2004 or early 2005, the doctors prepared a letter to send to their patients to advise them of the notification as, in my view, they were ethically obliged to do. The letter was not sent. . . . In the moment of truth that you faced when you drafted the letter and received advice from your counsel not to send the letter, you chose your personal interests over your ethical obligation and your fiduciary duty to your patients. That was wrong. . . . Accordingly, I will find and do hold that the failure

of the doctors to give notice to their patients for a five-year period after learning of the injections of the unapproved drugs is a factor in aggravation of sentence.

Feb. 9, 2010 Sentencing Tr., No. 1:09-cr-00425, ECF No. 14 at 38:6-39:1. Moreover, the court was not convinced that no patient had been harmed by the PSG Defendants' use of TRI-toxin, as one patient injected with the drug experienced swelling in her eye for two years:

The crux of [the doctors'] argument is that [they] determined that there was no harm which occurred to any of the patients. The record does not completely support this. . . . [T]here was a patient of Dr. Hargrave's . . . [who] complained to Dr. Hargrave after an injection in September of '04 that her eye remained swollen. . . . [T]his patient continued to complain of the swelling even two years after the injection, complained to the manufacturer of Botox, which she believed she had been injected with. That manufacturer contacted Dr. Hargrave for information and the response from Dr. Hargrave, as is indicated in the presentence report, was inaccurate and the patient, more importantly, was never told during this entire period that she had been injected with a substance which was not TRI-toxin [*sic*].

Id. at 33:3-34:1.

The PSG Defendants ultimately received the following sentences, which varied based on their roles at the clinic, and with respect to the doctors, the number of patients they injected with TRI-Toxin:

- Dr. William De Luca: three years' probation, 300 hours of community service, \$5,000 fine, \$106,686 joint and several restitution;
- Dr. Douglas Hargrave: three years' probation, 160 hours of community service, \$5,000 fine, \$106,686 joint and several restitution;
- Dr. Jeffrey Rockmore: three years' probation, 160 hours of community service; \$5,000 fine, \$106,686 joint and several restitution;
- Dr. Steven Lynch: two years' probation, 80 hours' community service, \$5,000 fine, \$106,686 joint and several restitution;
- Dr. John Noonan: one year probation, 40 hours of community service, \$5,000 fine, \$106,686 joint and several restitution;
- Peter Slattery (practice administrator): \$1,000 fine, \$106,686 joint and several restitution;

- Susan Knott (supervisory nurse): \$500 fine, \$106,686 joint and several restitution.
(a)

See id. at 51:16-52:21, 61:2-25, 70:4-25, 74:5-25, 79:10-80:11, 86:3-10, 91:10-21.

Thus, despite Lloyd's use of genuine Allergan-produced Botox, the absence of any harm to his patients, and the fact that he has not breached any ethical disclosure obligations, the Probation Office is recommending a sentence for Lloyd that is not only similar, but in some instances worse, than those issued to PSG Defendants. Notably, Slattery and Knott, while not physicians, were the only two defendants against whom the court did not impose an aggravating factor, and they both received sentences void of any terms of probation or community service.

CONCLUSION

For the foregoing reasons, Dr. Landsman respectfully requests that the Court impose the following sentence: compliance with the Forfeiture Order and a Special Assessment of \$25.

Dated: New York, New York
September 14, 2018

Respectfully submitted,

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